PATENT APPL. 09 836,750 Docket No. 1000-10-CO1



CERTIFICATE OF MAILING

Dated: June 17, 2003

Printed Name: Ann Rutledge

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: James P. Elia)
SERIAL NO.: 09/836,750) EXAMINER: E.C. Kemmerer, Ph.D
FILED: April 17, 2001)) GROUP ART UNIT: 1646
FOR: METHOD AND APPARATUS FOR INSTALLATION OF DENTAL IMPLANT)))

DECLARATION OF RICHARD HEUSER, M.D.

- I, Richard Heuser, declare as follows:
- I have offices at 525 North 18th Street, Suite 504, Phoenix, Arizona 85006. 1.
- My Curriculum Vitae is attached hereto as Exhibit A. 2.
- I have read and understood the disclosures of the above-referenced patent 3. application at page 20, line 10 through page 21, line 15; and page 44, line 19 through page 46, line 16. A copy of such disclosures is attached hereto as Exhibit B.
- I note that the disclosures referenced in above Paragraph 3 relate to using 4. a growth factor for promoting the growth of soft tissue and, more specifically, to a method of using a growth factor for growing muscle in a human heart.

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- 5. I am aware of and have considered the definition of *growth factor* in the specification of the above-referenced patent application at page 20, line 10 through page 21, line 15. Such definition is set forth in Exhibit C along with a definition from the medical dictionary, MEDLINE plus: Merriam-Webster Medical Dictionary. A service of the U.S. NATIONAL LIBRARY OF MEDICINE and the NATIONAL INSTITUTES OF HEALTH. I find that the dictionary definition is consistent with that contained at page 20, line 10 through page 21, line 15 of the above-referenced patent application. I believe that both definitions are appropriate for use in the field of tissue growth and would be understood by one skilled in the medical arts. Accordingly, I am adopting and utilizing the definition contained in the patent application throughout this declaration.
- 6. I have read and understood the claims set forth in Exhibit D and have been informed that such claims will be presented to the Patent and Trademark Office in the near future.
- 7. The materials included in attached Exhibit E illustrate that placement of a growth factor in a human patient causes muscle growth in a heart. These materials report work performed by reputable, skilled scientists and reputable organizations in the medical arts. Consequently, I believe that these reports would be recognized as clearly valid by one of ordinary skill in the medical arts because they report the results of scientific tests conducted by competent, disinterested third parties with use of proper scientific controls.
- 8. Based upon above Paragraphs 3-7, it is my opinion that introducing a growth factor into a human patient will predictably cause new muscle growth in the heart of the patient.

Docket No. 1000-10-CO1 HEUSER DECLARATION

- 9. Based upon above Paragraphs 3-6, it is my opinion that one skilled in the medical arts, armed with the knowledge in such paragraphs, would be able to practice the method set forth in Exhibit D without need for resorting to undue experimentation.
- 10. Declarant states that the above opinion was reached independently.

Declarant understands that (1) any willful false statements and the like made herein are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon, and (2) that all statements made of Declarant's own knowledge are true and that all statements made on information and belief are believed to be true.

Further Declarant sayeth not.

Date:

Richard Heuse